UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.

10/728,696

**Applicant** 

Williams

Filed

December 5, 2003 ٠:

Title

RECOMBINANT BOTULINUM TOXINS WITH A SOLUBLE

C-TERMINAL PORTION

TC/A.U.

1600/1645

Examiner

PORTNER, V.A.

Docket No.

D2939-CIPCONDIV1

**CERTIFICATE OF MAILING** 

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-

1450, on the date indicated below.

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Applicant wishes to call to the attention of the Examiner the documents cited on the accompanying Form PTO-1449. The cited documents were either identified in one or more related applications or are applications related to the above-identified application. communication is being submitted under 37 C.F.R. 1.97(c)(2). The Commissioner is hereby authorized to charge the necessary fee to Deposit Account No. 01-0885.

Each of these documents was cited in related (parent) application Serial No. 10/271,012 filed October 15, 2002. Therefore, no copies of these documents are submitted herewith. Applicant requests that each of these documents be made of record in the above-identified application.

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Respectfully submitted,

Registration No. 25,612

Stout, Uxa, Buyan & Mullins, LLP

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Frank J. La

Irvine, California 92618 Telephone: 949-450-1750 Form PTO-1449

Docket No.: D2939-CIPCONDIV1

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INFORMATION IN AN APPLICATION (Use several sheets if necessary)				Applicant: Williams				
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		5,071,759	12/1991	Rothman et al.				
		5,196,193	03/1993	Carroll				
		5,268,295	12/1993	Serroro				
		5,310,663	05/1994	Dobeli et al.				
		5,410,019	04/1995	Coy et al.				
		5,565,334	10/1996	Kufe et al.				
		5,837,264	11/1998	Becker et al.				
		5,837,265	11/1998	Montal et al.				
		5,874,415	02/1999	Kufe et al.				
		5,891,842	04/1999	Kream				•••
		5,919,665	07/1999	Williams				
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Docket No.: D2939-CIPCONDIV1 Application No.: 10/728,696 Form PTO-1449 Applicant: Williams INFORMATION DISCLOSURE CITATION Filing Date: December 5, 2003 Group Art Unit: 1645 IN AN APPLICATION (Use several sheets if necessary) **U. S. PATENT DOCUMENTS** EXAMINER INITIAL DOCUMENT NUMBER DATE NAME CLASS SUBCLASS **FILING DATE** IF APPROPRIATE 5,955,368 09/1999 Johnson et al. 02/2000 6,022,950 Murphy 09/2001 Dertzbaugh 6,287,566 04/2003 6,545,126 Johnson et al. 09/2004 6,787,517 Gil et al. FOREIGN PATENT DOCUMENTS DOCUMENT NUMBER COUNTRY CLASS SUBCLASS TRANSLATION DATE YES NO EP 0 209 281 01/1987 Europe EP 0 282 042 09/1988 Europe EP 0 593 176 04/1994 Europe GB 2 272 697 05/1994 **Great Britain** OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) ΑI Ford et al., (1991) Protein Expression & Purification, 2:95-107 Kimura et al., (1991) Applied & Enviro Microbio, 57(4):1168-72 ΑJ TaKaRa Shuzo Co. Catalog of TAKARA BIO INC at the web site: bio.takara.co.jp AK Nassau et al., (1996) J. Bacterio, 178(4):1047-52 AL AM Hill et al., (1996) Arch. Biochem. and Biophys. 336(2):283-9. AN Crowe et al., (1994) Methods in Molecular Biology, 31:371-387. AO Maisey et al., (1988) Eur. J. Biochem 177:683-691 Rudinger, J. in Peptide Hormones, Parsons, J.A. (Ed,) Univ. Park Press, Baltimore, MD pp. 1-7. AP Roitt, I. Essential Immun., 6<sup>th</sup> Edition, Blackwell Scientific Publications, Boston, MA, pp. 173-178. AQ AR LeClerc, C. et al. J. Immunol. 144(8): 3174-3182 AS Kleid, D.G. Annals NY Acad. Sci. 413:23-30. AT Siegel, L.J. Clin. Microbiol. 26: 2351-2356. Swiss-Prot Accession Number Q60393, Botulinum neurotoxin type G, Campbell, K et al (1993) ΑU cited therein. **EXAMINER DATE CONSIDERED** EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. include copy of this form with next communication to the applicant.

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